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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/769,823 | 02/02/2004 | Shuvo Roy | CCF-5519NP2 | 2275 |
| 26294 | 7590 | 02/14/2006 | EXAMINER | |
| TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P. | | | SZMAL, BRIAN SCOTT | |
| 1300 EAST NINTH STREET, SUITE 1700 | | | ART UNIT | |
| CLEVEVLAND, OH 44114 | | | PAPER NUMBER | |

3736

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/769,823

Applicant(s)

ROY ET AL.

Examiner

Brian Szmal

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,9 and 78-90 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,9 and 78-90 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/2/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 78, 79 and 82-86 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6, 7, 8, 10, 12 and 13 of U.S. Patent No. 6,706,005 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims disclose “a body for insertion between the adjacent bones”, whereas the issued patent discloses “a bone graft for insertion into the intervertebral space”. One of ordinary skill in the art would consider the bone graft to be an equivalent for a body.

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3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 9, 78-80, 82-86 and 90 are rejected under 35 U.S.C. 102(e) as being anticipated by Ishikawa et al (6,447,448 B1).

Ishikawa et al disclose miniature implanted orthopedic sensors and further disclose a body for insertion between adjacent bones; at least one sensor associated with the body, the sensor for generating an output signal in response to and indicative of a load being applied to the body through the adjacent bones; at least one telemetric device operatively coupled to the sensor, the telemetric device being operable to receive the output signal from the sensor and transmit an EMF signal dependent upon the output signal; the body comprises a prosthetic device for preserving motion between adjacent bones; a first sensor assembly located within the body; the first sensor assembly comprises a pressure sensor; a second sensor assembly located within the body, the telemetric device being located at the second sensor assembly; the first sensor assembly is maintained in physical communication with an interior surface of the body; an implant associated with the adjacent bones, the implant being external to the body; the implant is connected to the adjacent bones to stabilize the adjacent bones; at least one strain gauge mounted on the implant, the strain gauge for generating a second

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output signal in response to a load being applied to the implant, the strain gauge being electrically connected with the telemetric device; and the at least one telemetric device is located on the implant. See Column 5, lines 6-11, 33-43 and 56-66; Column 9, lines 30-33 and 54-61; and Column 10, lines 5-8.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 81 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa et al (6,447,448 B1) as applied to claims 78 and 86 above, and further in view of Guice et al (2002/0010390 A1).

Ishikawa et al, as discussed above, disclose implanted sensors, but fail to disclose the second sensor assembly is operatively connected to the first sensor via a tube; and the telemetric device is connected to the sensor via a tube such that the first sensor assembly is positioned inside a first end of the tube and a second end is attached to the implant.

Guice et al disclose a means for monitoring livestock and further disclose the second sensor assembly is operatively connected to the first sensor via a tube; and the telemetric device is connected to the sensor via a tube such that the first sensor

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assembly is positioned inside a first end of the tube and a second end is attached to the implant. See Paragraph 0190.

Since both Ishikawa et al and Guice et al disclose means for implanting sensors within a body, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Ishikawa et al to include the use of a tube to attach the sensors to one another as well as the telemetric means, as per the teachings of Guice et al, since it would provide a means of protecting the connection between the sensors and the telemetric device from the surrounding tissue.

7. Claims 88 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa et al (6,447,448 B1) and Guice et al (2002/0010390 A1) as applied to claim 87 above, and further in view of Keogh et al (5,925,552).

Ishikawa et al and Guice et al, as discussed above, disclose means for implanting sensors, but fail to disclose the tube has a biomolecular coating such that the tube is covered with a monolayer coating of a desired biomolecule; and the desired biomolecule is collagen.

Keogh et al disclose a means for attaching biomolecules to medical device surfaces and further disclose the tube has a biomolecular coating such that the tube is covered with a monolayer coating of a desired biomolecule; and the desired biomolecule is collagen. See Column 14, lines 31-45; and Column 17, lines 23-24.

Since Ishikawa et al and Guice et al disclose implanted sensors, and Keogh et al disclose means for coating implanted devices with a biomolecule, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify

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the combination of Ishikawa et al and Guice et al to include the use of a coating of a biomolecule on the tube, as per the teachings of Keogh et al, since it would provide a means of preventing rejection of the device as well as a means of allowing tissue ingrowth to prevent the sensor assembly from migrating from the implanted site.

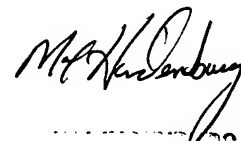
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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